DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 2, 2016

joimax® GmbH
% Mr. Gary Mocnik
Gary S. Mocnik and Associates
49 Coastal Oak
Aliso Viejo, California 92656

Re: K161378
Trade/Device Name: joimax® Electrosurgical Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 3, 2016
Received: October 4, 2016

Dear Mr. Mocnik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161378

Device Name
joimax® Electrosurgical Instruments

Indications for Use *(Describe)*

joimax® Bipolar Electrosurgical Instruments
The joimax® bipolar Vaporflex and Legato electrosurgical instruments are used for coagulation of soft tissue during open or minimally invasive surgical procedures when used in conjunction with a compatible radio frequency generator.
The joimax® bipolar electrosurgical instruments have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

Model JVP32024 Vaporflex® Probe, Bipolar, Ball Tip 320
Model JVP27525S Vaporflex® Probe, Bipolar, Ball Tip 275
Model JVP25024 Vaporflex® Probe, Bipolar, Ball Tip 250
Model JBPP27020 Legato® Probe, Bipolar, Ball Tip 270
Model JBPH352505 Legato® Handpiece, Bipolar, for Surgi-Max / Endovapor®
Model JVC35010 Vaporflex® Cable, for Surgi-Max / Endovapor
Model JVH32030 Vaporflex® Handle and Shaft, 320
Model JVHS27527S Vaporflex® Irrigation Shaft 275
Model JVHS32030 Vaporflex® Shaft 320
Model JVHS25030 Vaporflex® Shaft 250
Model JVUH10010 Vaporflex® Handle
Model JVHP10023 Vaporflex® Spare Sealing Rings

joimax® Monopolar Electrosurgical Instruments
The joimax® monopolar Legato electrosurgical instruments are used for cutting and/or coagulating soft tissue during open or minimally invasive surgical procedures when used in conjunction with a compatible radio frequency generator.

The joimax® monopolar electrosurgical instruments have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

Model JMPP27025 Legato® Probe, Monopolar
Model JMPH352504 Legato® Handpiece, Monopolar, for ValleyLab
Model VLT381645 Vaporflex® / Legato® Sterilization Tray
Model VLTC3816 Vaporflex® / Legato® Sterilization Tray with Lid

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

SUBMITTER:
joimax® GmbH
Amalienbadstrasse 41
RaumFabrik 61
76227 Karlsruhe, Germany

Contact person: Gary Mocnik
Phone: (949) 433-0413
Date prepared: October 31, 2016

II. DEVICE
Name of the device: joimax® Electrosurgical Instruments
Common of usual name: Electrosurgical probes and accessories
Classification name: Electrosurgical cutting and coagulation device
Regulatory Class: 2
Product Code: GEI

III. PREDICATE DEVICE
Primary Monopolar Predicate:
Aaron Reusable Electrosurgical Electrode (K014201)
Primary Bipolar Predicate:
Bi Polar TRIGGER-Flex Electrode (K003126)

IV. DEVICE DESCRIPTION
The joimax® Electrosurgical Instruments are comprised of a series of instruments to facilitate the delivery of electrical energy from an RF generator to the patient tissue for use in cutting and/or coagulation of tissue.

The joimax® Electrosurgical Instruments use Radio Frequency (RF) energy to induce thermal effects on tissue. The radio frequency is generated by high oscillating electrical current received from a commercially available RF generator.

The joimax® Probes are available in both monopolar and bipolar probe configurations. All joimax® Probes are designed for specific use with joimax® Handpieces. The joimax® Handpieces can be used with compatible commercially available surgical generators.

V. INDICATIONS FOR USE

joimax® Bipolar Electrosurgical Instruments

The joimax® bipolar Vaporflex and Legato electrosurgical instruments are used for coagulation of soft tissue during open or minimally invasive surgical procedures when used in conjunction with a compatible radio frequency generator.

The joimax® bipolar electrosurgical instruments have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

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joimax® Monopolar Electrosurgical Instruments

The joimax® monopolar Legato electrosurgical instruments are used for cutting and/or coagulating soft tissue during open or minimally invasive surgical procedures when used in conjunction with a compatible radio frequency generator.

The joimax® monopolar electrosurgical instruments have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

Model JMPP27025 Legato® Probe, Monopolar
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Model VLT381645 Vaporflex® / Legato® Sterilization Tray
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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Electrosurgical instruments, by nature, are instruments intended to deliver electrical energy directly to tissue to facilitate tissue cutting/coagulation in surgical applications.

The primary predicate devices (Aaron Reusable Electrosurgical Electrode, K014201; Bi Polar TRIGGER-Flex Electrode, K003126) and reference predicates (Arthrex Opes Electrodes and Accessories, K023986; Meddusa BiPolar System, K130110) were used to demonstrate substantial equivalence.

At a high level, the subject and predicate devices are based on the following same technological elements:

- All devices use electrical energy to generate high-frequency (RF) energy as a means to cut and/or coagulate tissue
- All instrument sets are comprised of a cutting tool (e.g. electrode), an ergonomic user interface (e.g. handpiece) and a connector (e.g. cable) to the generator
- The joimax® monopolar electrode, the Aaron and Arthrex Opes monopolar electrode predicates are all ball tipped.
- The ball diameter of the joimax® monopolar electrode (2.5 mm) is within the diameters (2 mm-5 mm) of the predicate device. The tip diameter (2.0 mm) for the joimax® bipolar electrodes is well within the established diameters of the predicate device (1-3 mm).
- The joimax® bipolar electrode shaft diameters (2.0 mm, 2.75 mm) are also within the established diameters of the predicate device (1-3 mm).
- The joimax® instruments shaft lengths (250-320 mm) are within the shaft length range of the predicate device (monopolar: 130-343 mm, bipolar 180-400 mm).
- The joimax® handpieces come in two configurations, namely a pencil design and a handled design. These designs are consistent with the handpiece designs of the predicate device which also come in pencil or handled configurations.
- The connecting cable length of the joimax® electrosurgical instruments is 3.5 meters, which is similar to the predicate Aaron device cable length and the Trigger-Flex cable length of approximately 3 meters.
- The joimax® handpieces and the predicate Arthrex Opes handpieces are provided non-sterile and are intended to be sterilized by the user.

VII. PERFORMANCE DATA

Biocompatibility Testing

The biocompatibility evaluation for the Brand X device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of

testing included the following tests:

- Cytotoxicity
- Irritation
- Sensitization
- Acute Systemic Toxicity

The joimax electrosurgical instruments are considered direct tissue contacting for < 24 hours.

Sterilization/Shelf-Life

The bipolar instruments were validated to achieve a sterility assurance level of 10^{-6} using ISO 11137-1/-2 (bipolar instruments). The disposable monopolar instruments were adopted into a validated EO cycle following AAMI TIR 28:2009. The reusable instruments moist heat sterilization cycle was validated per ISO 17665-1. Packaging validation was performed to ensure the devices provided sterile maintain their sterile barrier integrity following the requirements outlined in ISO 11607-1.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the joimax® electrosurgical instruments. The instruments comply with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

Performance Testing

Performance testing was conducted for the joimax® Electrosurgical Instruments to demonstrate the suitability of the device for its intended use. The results of the testing indicate that the joimax® Electrosurgical Instruments is substantially equivalent to the predicate devices and is safe and effective for its intended use.

Dimensional and Physical Properties Verification was performed to demonstrate the instruments met their specifications and confirmed the physical properties of the devices. Ex-vivo testing was conducted using multiple types of soft animal tissue (kidney, liver and muscle tissue). Testing included all ranges of relevant parameters, such as power settings, activation duration, and waveforms / frequencies. Effect on tissue was assessed and determined to be highly comparable to the predicate device.

The joimax® Electrosurgical Instruments met all specified criteria and did not raise new safety or performance questions. Based on the design verification performance the joimax® Electrosurgical Instruments was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. CONCLUSIONS

The testing performed for the joimax® Electrosurgical Instruments demonstrated that the performance of the joimax® Electrosurgical Instruments is equal to the legally marketed predicate devices.